



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Foods
Food and Drug Administration
Silver Spring, MD 20993

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James H. Skiles
Vice President and General Counsel
Grocery Manufacturers Association
1350 I Street, Suite 300
Washington, DC 20005

Erik R. Lieberman
Regulatory Counsel
Food Marketing Institute
2345 Crystal Drive, Suite 800
Arlington, VA 22202

Dear Mr. Skiles and Mr. Lieberman:

This letter is in response to your letter dated August 17, 2011, and other communications requesting that the Food and Drug Administration (FDA or the Agency) exercise enforcement discretion for certain aspects of the Nutrition Keys front-of-pack labeling program.

Nutrition Keys (Facts Up Front¹) is a voluntary labeling program, developed by the Grocery Manufacturers Association (GMA) and the Food Marketing Institute (FMI), which provides information on the principal display panel of food labels about the amounts of important nutrients in the food. Products labeled with Nutrition Keys include four "Basic Icons" on the principal display panel. The four "Basic Icons" provide information from the Nutrition Facts panel on calories, saturated fat, sodium and total sugar content.

In addition to the "Basic Icons," some products may display up to two "Optional Icons," which may provide information from the Nutrition Facts panel on potassium, dietary fiber, protein, vitamin A, vitamin C, vitamin D, calcium, or iron.

Under the rules of the Nutrition Keys program as described in your letter and the accompanying "Style Guide,"² participating companies are to present the Basic Icons in a standardized format that includes all four icons on all their eligible products, rather than selectively on some products. We understand that, after a phase-in period, you expect broad implementation of the

¹ News Release, "GMA and FMI Announce 'Facts Up Front' as Theme for Front-of-Pack Labeling Program Consumer Education Campaign," Sept. 22, 2011 (<http://www.gmaonline.org/news-events/newsroom/gma-and-fmi-announce-facts-up-front-as-theme-for-labeling-program-consumer->).

² Nutrition Keys Final Draft Style Guide for Implementers, May 3, 2011.

Nutrition Keys, resulting in a uniform system that will make information on the amounts of nutrients in a food available to consumers at a glance in the four "Basic Icons".

You have requested that FDA exercise enforcement discretion with respect to certain aspects of its nutrition labeling regulations in order to facilitate implementation of the Nutrition Keys program, namely:

1. Use of the four Nutrition Keys Basic Icons (calories, saturated fat, sodium, and total sugars), alone or accompanied by up to two Nutrition Keys Optional Icons, without declaration of polyunsaturated fat and monounsaturated fat in the Nutrition Facts panel as required by 21 CFR 101.9(c)(2)(iii) and (iv).
2. Use of the four Nutrition Keys Basic Icons, unaccompanied by any Optional Icons, without the disclosure statement required by § 101.13(h) when the nutrient content of the food exceeds specified levels of total fat, saturated fat, cholesterol, or sodium.
3. Use of the four Nutrition Keys Basic Icons, alone or accompanied by up to two Nutrition Keys Optional Icons, without disclosure of the level of total fat and cholesterol in immediate proximity to the saturated fat icon as required by § 101.62(c).

You stated that you do not believe any of these declarations or disclosure statements are required under the Federal Food, Drug, and Cosmetic Act (FDCA) because the Basic Icons constitute non-promotional disclosures, not nutrient content claims. In the alternative, if FDA determines that any of these declarations or disclosure statements *are* required, you request that the Agency exercise enforcement discretion to help ensure that food companies have no disincentives or barriers to rolling out the Nutrition Keys program on the labels of all eligible food products. You further state that the exercise of enforcement discretion is warranted because this program will assist the Agency in accomplishing its public health objectives.

FDA views the Nutrition Keys Basic Icons (calories, saturated fat, sodium and total sugar content) and Optional Icons as nutrient content claims subject to all the requirements of the FDCA and the Agency's regulations. We recognize, however, that standardized, non-selective presentation of the four Basic Icons on a company's product line would alleviate some of FDA's concern regarding the potential for product labeling to mislead consumers by presenting only "good news" about nutrient content on the front of the package, which is the concern that the regulations governing nutrient content claims were intended to address. We also recognize that the standardized, non-selective presentation of the four Basic Icons on a company's entire product line, if widely adopted by the food industry in a uniform manner, may contribute to FDA's public health goals by fostering awareness of the nutrient content of foods in the marketplace and assisting consumers in making quick, informed, and healthy food choices.

As of the date of this letter, FDA intends to exercise enforcement discretion as outlined in the numbered points above with respect to firms that participate in and comply with the terms of the Nutrition Keys program, including use of the four Basic Icons on virtually all eligible products. We believe that this will facilitate participation in a positive effort to provide consumers more ready access to information about the nutrient content of packaged foods, without compromising

consumer protection. A key consideration in our decision is that the disclosure statement referring consumers to the Nutrition Facts panel of the food label will continue to be required on products that bear Optional Icons and that exceed the disclosure trigger levels of total fat, saturated fat, cholesterol, or sodium established in 21 CFR 101.13(h). In addition, all other nutrient content claims used on the food label or in other labeling will be expected to comply with the relevant regulations on the use of such claims.

It is FDA's understanding that GMA and FMI will use their best efforts to ensure that participating companies use the Nutrition Keys program as outlined in the Style Guide. Based on information you have provided, we understand that the steps you are taking to ensure compliance include, among others, an online training requirement for all participating companies, a label pre-clearance requirement for participating companies who are not members of GMA or FMI, consultations with GMA and FMI staff, telephone and email hotlines for members of the public and industry to ask questions and comment on Nutrition Keys program administration and integrity, targeted outreach to companies who plan to use Nutrition Keys Optional Icons, and a market surveillance program to assess the pace and scope of implementation and monitor individual labels for compliance with program rules.³

FDA does not intend to exercise enforcement discretion with respect to companies that misuse the Nutrition Keys labeling system in a manner that misleads consumers or otherwise violates the FDCA. Over time, FDA intends to assess whether the Nutrition Keys labeling system is being applied in a manner that promotes public health and is useful to consumers. We understand that GMA and FMI will be conducting their own evaluation of the system to determine whether consumers notice, understand and use this front-of-pack labeling system. You have invited us to work with you on this evaluation,⁴ and we will be happy to do so. We look forward to reviewing and learning from that evaluation as well as any other evaluations or reviews that are conducted. As appropriate, FDA will evaluate its exercise of enforcement discretion as the Agency gains more experience with the Nutrition Keys program.

We look forward to working with you to ensure that consumers get the reliable and standardized information they need to make healthy food choices.

Sincerely,



Michael R. Taylor
Deputy Commissioner for Foods

³ "Compliance Monitoring Program - Nutrition Keys," attachment to email from Joseph A. Levitt, Hogan Lovells, to Jessica Leighton, FDA, July 20, 2011.

⁴ Email from Joseph A. Levitt, Hogan Lovells, to Jessica Leighton, FDA, July 20, 2011.